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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/559,784

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Mitsuko Kosaka

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EDWARDS ANGELL PALMER & DODGE LLP
P.O. BOX 55874
BOSTON, MA 02205

EXAMINER

DUTT, ADITI

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/559,784	Applicant(s) KOSAKA, MITSUKO	
	Examiner Aditi Dutt	Art Unit 1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 June 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 11-14 is/are pending in the application.
- 4a) Of the above claim(s) 1-6 and 11-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7 and 8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/30/09;6/2/09</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Claims

1. The amendment filed on 16 March 2009 has been entered into the record and has been fully considered. Claims 9-10 have been cancelled. Claims 7-8 are amended. The first line of "Remarks" has a typo "11-**24**" instead of "11-14".
2. Claims 7-8, drawn to a method for producing retinal nerve cells by isolating and differentiating iris pigmented epithelial cells in a serum free culture medium, are being considered for examination in the instant application.
3. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicants response and withdrawn.
4. Applicant's arguments filed on 16 March 2009, have been fully considered. New grounds of objection and rejection are as follows.

New Objections

Information Disclosure Statement

5. The Information disclosure statements dated 30 April 2009 and 2 June 2009 have been considered and entered into the record. However, because the two statements are duplicated, the IDS dated 30 April 2009 is crossed off.

Specification

6. The disclosure is objected to because of the following informalities:

The amended title of 16 March 2009 has a typographical error on line 1 - word/words found missing after the term "retinal".

Appropriate correction is required.

Response to Amendment

Withdrawn objections and/or rejections

7. Upon consideration of the Applicant's amendment, all claim objections and rejections, not reiterated herein have been withdrawn, as overcome by cancellation and/or amendment of claims (16 March 2009).
8. Upon consideration of Applicant's amendment of claims 7-8 to recite the specific culture medium requirements, the rejection under 35 U.S.C. 112, first paragraph - scope of enablement and written description, is withdrawn.

Rejections maintained

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to

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a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The rejection of claims 7-10, are rejected under 35 U.S.C. 103(a) as being unpatentable over Kosaka et al. (Exp Cell Res 245: 245-251, 1998) in view of Haruta et al., (Nat Neurosc 4: 1163-1164, 2001), is applied to the amended claims 7-8, for reasons of record in the Office Action, dated 8 January 2009.
10. Applicant's arguments are based on the current claim amendments. Specifically Applicant argues that the present invention as recited in amended claim 7 is drawn to the use of iris pigmented epithelial cells "not being subjected to a gene transfer", while the Haruta reference teaches differentiation into retinal nerve cells after a "Crx gene is transferred and forcibly expressed" in the iris-derived cells. Applicant also argues that Haruta teaches iris derived cells that are different from the claimed iris pigmented epithelial cells, because the cells of Haruta do not produce retinal photoreceptor cell marker rhodopsin, without the Crx gene transfer. Applicant concludes that the invention as currently amended in claim 7 is non-obvious over the prior art teachings because the skilled person would not accomplish the same results as claimed, without forcibly expressing the Crx gene in the iris-derived cells. As such the rejection is requested to be withdrawn.
11. Applicant's arguments are fully considered but not found to be persuasive, because arguments that rely on particular distinguishing features are not persuasive when those features are not recited in the claims. Applicant's arguments are largely directed to the Haruta reference, emphasizing the

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limitations inserted in the current claim amendments. As stated in the previous Office Action, Haruta et al teach the plating and maintenance of iris tissue from adult rats in serum free culture medium containing bFGF or FGF2, resulting in the proliferation of cells as a monolayer (Figure 1a, page 1163, para 2). Haruta et al. also teach that the iris derived cells are positive for a retinal ganglion cell marker, neurofilament 200, wherein such differentiation into a retinal nerve cell is accomplished without any gene transfer. The previous Office Action does not describe Figures 2 or 3, nor does it describe the differentiation to retinal photoreceptor cells from iris derived cells by transferring a Crx gene, as extensively argued by Applicant. Furthermore, the claims as amended do not require the differentiation to retinal photoreceptor cells, nor do they specifically recite that the retinal nerve cells are photoreceptor cells that produce rhodopsin. Therefore, Applicant is diverting the arguments to the newly amended subject matter, side-tracking the arguments presented in the previous Office Action.

12. The instant claims require a method for producing retinal nerve cells by isolating and differentiating iris pigmented epithelial cells, wherein the differentiation is induced by adherent culturing in a serum-free culture medium containing one of FGF2, FGF9 and CNTF. Based on the definition provided in the instant disclosure, a nerve cell can comprise neurons as well as non-neuronal or glial cells (para 0122, 0123), and a retinal nerve cell can comprise a retinal visual cell, bipolar cell, Muller glial cells, etc. (para 0040). Additionally iris-derived cells are broadly defined as comprising IPE cells, and Kosaka et al teach

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the isolation of IPE cells. It is to be noted that USPTO personnel are to give claims their broadest reasonable interpretation in light of the supporting disclosure. *In re Morris*, 127 F.3d 1048, 1054-55, 44 USPQ2d 1023, 1027-28 (Fed. Cir. 1997). Narrow limitation contained in the specification cannot be inferred in the claims where the elements not set forth in the claims are linchpin of patentability. See *In re Philips Industries, Inc. v. State Stove & Mfg. Co.*, 522 F.2d 1137, 186 USPQ 458 (CA6 1975), 237 PTJA A-12. While the claims are to be interpreted in light of the specification, it does not follow that limitations from the specification may be read into claims. On the contrary, claims must be interpreted as broadly as their terms reasonably allow. See *Ex parte Oetiker*, 23 USPQ2d 1641 (BPAI, 1992). Applicant is reminded that the claims define the subject matter of his invention and that the specification cannot be relied upon to read limitations into the claims.

In view of the above discussion, it is reiterated from the last Office Action that:

It would have been, therefore, obvious to the person of ordinary skill in the art at the time the claimed invention was made to modify the method of inducing differentiation of IPE cells to lens cells by adherent or monolayer culture method in medium containing serum as taught by Kosaka et al., to the monolayer culture in a serum free medium of Haruta et al., whereby the iris derived cells differentiate to retinal cells expressing neuronal antigen (i.e. inherently retinal nerve cells). The person of ordinary skill in the art would have been motivated because IPE and the neural retina have a common developmental origin, thereby giving rise to retinal neurons (Haruta et al. page 2163).

Because, the source of the cells and culture conditions in the prior art teachings and the currently claimed invention are the same, the claimed invention as a

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whole stands *prima facie* obvious over the combined teachings of the prior art and stay rejected.

Conclusion

13. No claims are allowed.
14. **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).
15. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.
16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aditi Dutt whose telephone number is (571) 272-9037. The examiner can normally be reached on Monday through Friday, 9:00 a.m. to 5:00 p.m.
17. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker, can be reached on (571) 272-0911. The

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fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

18. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov/>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AD
24 June 2009

/Jeffrey Stucker/

Supervisory Patent Examiner, Art Unit 1649